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ATTORNEY DOCKET NO. 10030208-1

*IFW*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): James M. Minor

Serial No.: 10/640,081

Examiner: Shibuya, Mark Lance

Filing Date: August 13, 2003

Group Art Unit: 1639

Title: Methods and System for Multi-Drug Treatment Discovery

COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria VA 22313-1450

TRANSMITTAL LETTER FOR RESPONSE/AMENDMENT

Sir:

Transmitted herewith is/are the following in the above-identified application:

- ☒ Response/Amendment ☐ Petition to extend time to respond  
☐ New fee as calculated below ☐ Supplemental Declaration  
☐ No additional fee (Address envelope to "Mail Stop Amendments")  
☐ Other: (Fee \$ \_\_\_\_\_)

CLAIMS AS AMENDED BY OTHER THAN A SMALL ENTITY						
(1) FOR	(2) CLAIMS REMAINING AFTER AMENDMENT	(3) NUMBER EXTRA	(4) HIGHEST NUMBER PREVIOUSLY PAID FOR	(5) PRESENT EXTRA	(6) RATE	(7) ADDITIONAL FEES
TOTAL CLAIMS		MINUS		= 0	X 50	\$ 0
INDEP. CLAIMS		MINUS		= 0	X 200	\$ 0
<input type="checkbox"/> FIRST PRESENTATION OF A MULTIPLE DEPENDENT CLAIM					+ 360	\$ 0
EXTENSION FEE	1 <sup>ST</sup> MONTH 120.00 <input type="checkbox"/>	2 <sup>ND</sup> MONTH 450.00 <input type="checkbox"/>	3 <sup>RD</sup> MONTH 1020.00 <input type="checkbox"/>	4 <sup>TH</sup> MONTH 1590.00 <input type="checkbox"/>		\$ 0
OTHER FEES						\$ 0
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT						\$ 0

Charge \$0 to Deposit Account 50-1078. At any time during the pendency of this application, please charge any fees required or credit any over payment to Deposit Account 50-1078 pursuant to 37 CFR 1.2 5. Additionally please charge any fees to Deposit Account 50-1078 under 37 CFR 1.16, 1.17, 1.19, 1.20 and 1.21. A duplicate copy of this transmittal letter is enclosed.

Respectfully submitted,

James M. Minor

By

Alan W. Cannon for John Brady  
Attorney/Agent for Applicant(s)

I hereby certify that this correspondence is being Deposited  
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Typed Name: Maria J. Sousa

Signature:

*[Handwritten Signature]*

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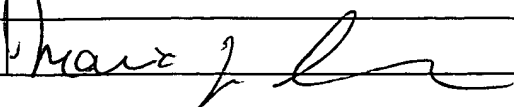
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**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:  
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Typed or Printed Name	Maria J. Sousa		
Signature		Date	7/12/2006

<b>RESPONSE TO RESTRICTION REQUIREMENT</b>  Address to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Attorney Docket Confirmation No.	10030208-1 7915
	First Named Inventor	Minor
	Application Number	10/640,081
	Filing Date	08/13/2003
	Group Art Unit	1639
	Examiner Name	Shibuya, Mark Lance
	Title	Methods and System for Multi-Drug Treatment Discovery

Sir:

This is in response to the Restriction Requirement dated June 14, 2006 for which a one-month period for response was given making this response due on or before July 14, 2006.

**THE RESTRICTION REQUIREMENT**

In the Official Action dated June 14, 2006, the Examiner required an election of one of the following inventions that were identified by the Examiner:

Group I – Claims 1-23 drawn to a method for screening a combination of treatments comprising providing differential expression for diseased tissue samples.

Group II – Claims 24-29 drawn to a system for screening a combination of treatments to specifically target a disease process comprising means for generating a phenotypic signature representing differential expression levels of each of a plurality of disease tissue samples.

Group III – Claims 30-34 drawn to a method for determining phase relationships between treatment responses of diseased tissues to treatments thereof.

Group IV – Claims 35-37 drawn to a combination of compounds for treating cancer.

Group V – Claims 38-41 drawn to a computer readable medium carrying instructions for screening a combination of treatments to specifically target a disease process.

The Examiner further required an election of species among three different groups of species that the Examiner identified.

In the first group, the Examiner required the election of a single species from the group consisting of: a drug, a combination of drugs, a compound, a combination of compounds, radiation, a genetic sequence, a combination of genetic sequences, heat, cryogenics, and a combination of two or more of any of the previous members in this group.

The Examiner indicated that claims 1, 4, 21, 22, 30 and 33 are generic to this group of species.

In the second group, the Examiner required the election of a single species from the group consisting of: a combination of compounds for treating cancer, said combination comprising at least two compounds selected from the group consisting of: Sevinon, or a family member thereof, Paclitaxel-Taxol, Gemcitabine and Mitoxantrone.

The Examiner indicated that claim 35 is generic to this group of species.

In the third group, the Examiner required the election of a single species from the group consisting of: a combination of claim 35, wherein said combination comprises a compound from each of Sevinon, or a family member thereof, Paclitaxel-Taxol, Gemcitabine and Mitoxantrone.

The Examiner indicated that claims 35 and 36 are generic to this group of species.

In response to the requirement to elect an invention and species, Applicant elects Group I, claims 1-23; species – a combination of compounds, species - Sevinon, or a family member thereof, and Paclitaxel-Taxol for the species requirement in paragraph 4 on page 6; and species - Sevinon or a family member thereof and Paclitaxel-Taxol and Gemcitabine and Mitoxantrone for the species requirement indicated at paragraph 5, page 7, with traverse. It is respectfully submitted that all of claims 1-23 read on all of the elected species indicated above.

The Examiner indicated that the invention of Group I and the inventions of Groups II and V are related as process and apparatus for its practice. The Examiner asserted that these groups are distinct

since the system comprising means for screening a combination of treatments of the invention of Group II and the computer readable medium of the Invention of Group V can be used to determine the phase relationships between treatment responses, which is a materially different process from that of screening combinations of treatments, as in Group I.

Applicants respectfully traverse these assertions. It is respectfully submitted that the invention of Group I can also be used to determine phase relationships between treatment responses, e.g., see claim 5. Accordingly it is respectfully submitted that the Examiner has not established distinctness between Groups I, II and V, and the Examiner is respectfully requested to consider all claims from all of these “Groups” together.

With regard to Groups II and V, the Examiner asserted that these groups were related as combination and subcombination. Additionally, the Examiner asserted: “In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because combination, which is the Invention of Group II, is a system comprising at least four different means for various aspects of screening a combination of treatments to specifically target a disease process and does not specifically claim a limitation to a computer readable medium carrying instructions for screening a combination of treatments that is the subcombination”.

This argument is not understood. Group V does not specifically claim a limitation to a computer readable medium carrying instructions for screening a combination of treatments either, as the Examiner has taken this language from the preamble of claim 38. Moreover, independent claim 24 of Group II recites in the preamble a system for screening a combination of treatments to specifically target a disease process. Accordingly, it is respectfully submitted that the Examiner has not established distinctness between Groups II and V and is requested to consider the claims of these groups together.

With regard to the election of species requirement on page 6, paragraph #3, this requirement is not understood. Claim 4 is written as a Markush style claim, i.e., “selected from the group consisting of: a drug, a combination of drugs, a compound, a combination of compounds, radiation, a genetic sequence, a combination of genetic sequences, heat, cryogenics and a combination of two or more of any of the previous members in this group”. Accordingly, the limitations of this claim can be met by finding any one of the members of the Markush group, and therefore the election of species requirement is not understood. The Examiner is respectfully requested to clarify this requirement, or withdraw it, in the next Official Action.

Similarly, with regard to the election of species requirement on page 6, paragraph #4, this requirement is not understood. Claim 35 is written as a Markush style claim, i.e., “at least two

compounds selected from the group consisting of: Sevinon, or a family member thereof; Paclitaxel-Taxol; Gemcitabine and Mitoxantrone". Accordingly, the limitations of this claim can be met by finding any reference that includes a combination of compounds that has at least two compounds selected from the recited Markush group, and therefore the election of species requirement is not understood. The Examiner is respectfully requested to clarify this requirement, or withdraw it, in the next Official Action.

As to the election of species requirement on page 7, paragraph #5, this requirement is not understood. It is respectfully submitted that claim 36 recites only one species, i.e., a combination comprising a compound from each of Sevinon, or a family member thereof; Paclitaxel-Taxol; Gemcitabine and Mitoxantrone, and that it is therefore not possible to make an election of species in this case. Accordingly, the Examiner is respectfully requested to clarify this requirement, or withdraw it, in the next Official Action.

### **Conclusion**

Applicants respectfully submit that a proper response has been made to the Restriction Requirement. Applicants further respectfully submit that the Examiner has not shown distinctness among at least Groups I, II, III and V and that at least the claims of all of these groups should be considered together with the claims of elected Group I. Applicants further respectfully submit that none of the election of species requirement are proper, for the reasons noted above, and should be withdrawn. Finally, Applicants also respectfully request that the claims of Group IV be considered together with the claims of Groups I, II, III and V, as the search required for Group IV would be overlapping and not pose a serious burden to the Office.

Applicants respectfully submit that all of the claims in this application are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078, order number 10030208-1.

Respectfully submitted,  
James Minor et al.

Date: \_\_\_\_\_

7/12/06

By: \_\_\_\_\_



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